K111260

510 (K) Summaries

JUL 26 2012

A/C Enzymatic Vitamin B6 Assay

Summary of Safety and Effectiveness Information Supporting a Substantially Equivalent Determination

1. Submitter's Name:

Submitter: A/C DIAGNOSTICS LLC
7917 Ostrow Street
San Diego, CA 92111
Phone: (858) 654-2555
Fax: (858) 268-4175
Email: all@anticancer.com

Contact Person:
Qinghong Han M.D.
Principal Investigator of the Device

Date of Summary Preparation: March 15, 2011

2. Device Information

Device Name: A/C Enzymatic Vitamin B_6 Assay

Classification Panel: Clinical Chemistry

Device Classification: II

4. Regulatory Information:

Product Code: JIT, Regulation Section: 21 CFR 862.1150- Calibrator

JJX, Regulation Section: 21 CFR 862.1660– Quality Control Material (Assayed and Unassay)

3. Predicate Device Information

(1) Predicate device name:

BUHLMAA Vitamin B_6 REA
American Laboratory Products CO., LTD
PO BOX 451
Windham, NH 03087
Tel: (603) 893-8914

(2) Predicate 510(k) number
K955561

4. Information of Manufacturer
Manufacturer: Bioserv Corporation
5340 Eastgate Mall
San Diego, CA 92121
Tel: (858) 450-3123
Fax: (858) 450-0785
FDA establishment registration number: US FDA 2027352
Contact Person: Mary Richardson
Quality Assurance Manager

5. Statement of Intended Use

The A/C Enzymatic Vitamin B_6 Assay is intended for the quantitative in vitro diagnostic determination of pyridoxal 5'-phosphate (PLP, vitamin B_6) in EDTA-human plasma. The device will be used to monitor PLP concentrations in plasma for aid in diagnosis of vitamin B6 deficiency. The A/C Enzymatic Vitamin B_6 Assay is for **IN VITRO DIAGNOSTIC USE ONLY**.

6. Description of Device

The A/C Enzymatic Vitamin B_6 Assay is calibrated with external standardization and matrix-matched calibration solutions. Two sources of quality control material (A low

and high level of PLP) are assayed in each run together with A/C Calibrators and samples for the verification of the accuracy and precision of the A/C Enzymatic Vitamin B_6 Assay.

The A/C Enzymatic Vitamin B_6 Assay uses the apo form of recombinant PLP-dependent enzyme, homocysteine-α,γ-lyase (rHCYase). The restoration of enzymatic activity by reconstitution of the holo-enzyme is linearly dependent on the amount of PLP bound to apo-enzyme. Nanomolar concentrations of PLP can then be measured by the conversion of millimolar concentrations of homocysteine to hydrogen sulfide, which is determined using DBPDA, the combination of which forms a chromophore, the absorbance is read with 96-well plate absorbance reader.

The A/C Enzymatic Vitamin B_6 Assay is a three-step reaction with four reagents, which runs at 37°C or room temperature. The total assay takes 90 minutes. The assay can be performance on 96-well absorbance reader with 660-690$_{nm}$ filter.

7. Method comparison

To establish equivalence to an existing device, and thus establish the safety and effectiveness, the A/C Enzymatic Vitamin B_6 Assay was compared to ALPCO Vitamin B_6 REA method (K# 955561).

The comparison of the A/C Enzymatic Vitamin B_6 Assay to the ALPCO Vitamin B_6 REA assay was carried for fifty four EDTA-plasma samples. Each sample was analyzed in duplicate with both methods. The correlation and regression analysis yielded $y = 0.969x + 7.6$ with a correlation coefficient of $r = 0.909$. The bias analysis of both methods by the difference (A/C Enzymatic B_6 – ALPCO B_6) *vs* PLPCO B_6 REA is shown in the Difference plot. The range of values was 16.3 – 189.3 nmol/L (mean = 66.3) for the A/C Enzymatic Vitamin B_6 Assay and 15.8 -185.8 nmol/l (mean = 68.7) for ALPCO Vitamin B_6 REA Assay. The average difference exhibited by A/C Enzymatic Vitamin B6 Assay and ALPCO B6 REA in this study was 2.42 nmol/L.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration

10903 New Hampshire Avenue
Silver Spring, MD 20993

AntiCancer, Inc
c.o Dr. Qinghong Han
7917 Ostrow St.
San Diego, CA 92111

JUL 26 2012

Re: k111260
Trade Name: A/C Enzymatic Vitamin B6 Assay
Regulation Number: 21 CFR §862.1810
Regulation Name: Vitamin B12 test system
Regulatory Class: Class II
Product Codes: CDD
Dated: July 2, 2012
Received: July 12, 2012

Dear Dr Han:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (301) 796-5760. For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance...

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-5680 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm

Sincerely yours,

Courtney H. Lias, Ph.D.
Director
Division of Chemistry and Toxicology Devices
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications for Use Form

510(k) Number (if known): K111260

Device Name: A/C ENZYMATIC VITAMIN B_6 ASSAY

Indications for Use:

INDICATION FOR USE STATEMENT:

- The A/C Enzymatic Vitamin B6 Assay is intended for the quantitative determination of pyridoxal 5'-phosphate (PLP, vitamin B_6) in EDTA-plasma.
- The device will monitor vitamin B_6 (PLP) status in human plasma for aid in diagnosis of vitamin B_6 deficiency.
- The A/C Enzymatic Vitamin $_{B6}$ Assay is for **IN VITRO DIAGNOSTIC USE ONLY.**

Prescription Use X AND/OR Over-The-Counter Use _____

(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Division Sign-Off

Office of In Vitro Diagnostic Device

Evaluation and Safety

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